

Other categories in the TDP, pleural disease levels 1, 2 and 3, also require bilateral pleural disease, excluding unilateral disease. These classifications too are scientifically arbitrary.

The ILO (2000) classifications recognize unilateral disease. Its pleural thickening scoring system, p.7, refers to "an obliterated costophrenic angle" implying that one angle is sufficient. Similarly the scoring system, p.7, for diffuse pleural thickening records measurements "separately for the right and left side," implying that a single 3mm width in a single "extent > 25%" will suffice. However, the TDP does not follow ILO (2000), as the TDP excludes unilateral disease.

The exclusion of unilateral disease is scientifically arbitrary and has no relationship to the treatment of asbestos disease patients.

79. The TDP omits diffusion capacity (DLCO) as a measure of severity. The TDP, p. 26, for "Severe Disabling Pleural Disease" Level 4B, requires Total Lung Capacity (TLC) or Forced Vital Capacity (FVC) under 65. Of all lung function tests, the three most important in asbestos disease are FVC, TLC, and diffusion capacity. The Fishman text, p. 950, states "The characteristic pulmonary function changes of asbestosis are a restrictive impairment with a reduction in lung volumes (especially FVC and TLC), decreased diffusion capacity, and arterial hypocemia." ATS (2004) Official

Statement adopted the above quoted statement at p. 697. The 2005 Public Citizen comment by Dr. Michael Harbut, Dr. Philip J. Landrigan, Dr. Alan C. Whitehouse and Dr. L. Christine Oliver states that DLCO is "essential to determine how badly a person's lungs are impaired." Exh. 16. The TDP's omission of diffusion capacity as a measure of severity is not consistent with the medical literature, or clinical practice.

Diffusion Capacity (DLCO) is a particularly important indicator of the severity of impairment in the Libby asbestos disease patients. In some cases, there is significant asbestos disease on the chest x-ray and only the DLCO is reduced, not the FVC or TLC. Some patients with severe shortness of breath are severe only in the DLCO defect. In Whitehouse (2004), p. 224, 76% of the 123 patients had progressive loss of lung function. Losses were about the same for each of FVC, TLC and DLCO at 2-3% per year.

In the CARD mortality study, among those who died of non-malignant asbestos disease, 47% (29/61) had only DLCO under 65 (out of FVC, TLC and DLCO). These patients were all severe and are now dead. Yet, none would qualify as a "severe pleural" under the TDP because they did not happen to have FVC or TLC under 65. In terms of clinical medicine, the exclusion is scientifically arbitrary.

80. The TDP excludes those with an obstructive component to their

asbestos pleural disease. TDP, p. 26, for "Severe Disabling Pleural Disease", Level 4B, and for moderate "pleural disease," Level 3, requires an " $FEV_1/FVC$  ratio  $> 65\%$ ." As discussed above in § H Obstructive Defect from Asbestos Related Disease, an obstructive pattern is common with ARD, particularly in the Libby cohort. To exclude those with significant Asbestos Pleural Disease and an obstructive component would be scientifically arbitrary.

The Fishman text, p. 604, states: "The hallmark of the obstructive pattern is a reduction in the  $FEV_1/FVC$  percentage. . . Typically, all three lung volumes, residual volume, FRC, and TLC are increased." Here, increased means abnormal, or over 120% of predicted. A mild reduction in  $FEV_1/FVC$  ratio may be seen as a ratio of 60-70. Markowitz et al (1997), p. 102, uses a ratio of 70 as normal for ages under 60 and a normal of 65 for those 60 or older.

In the CARD mortality study, among those who died of non-malignant asbestos disease, 40% (29/72) had an  $FEV_1/FVC$  ratio of 65 or less.

The problem is that smoking disease may also cause reduction in the ratio, and there may be an interest in excluding persons with minimal asbestos disease and predominately smoking disease. A more scientifically sound approach would be to exclude those with a ratio under 65 and TLC abnormally high (over 120). Of the CARD mortality study non-malignant deaths, 10% (6/61) of those with full lung function tests had a total lung

capacity over 120. As I understand it, these six would go to individual review.

No requirement of an FEV<sub>1</sub>/FVC ratio over 65 is included as a necessary condition to the diagnosis of asbestos-related disease in the ATS (2004) Official Statement on standard practice in diagnosis of ARD. No diagnostic definition of ARD includes a requirement that the FEV<sub>1</sub>/FVC ratio be over 65. Excluding those patients with a ratio under 65 from the pleural disease classification is scientifically arbitrary. The interest in excluding those with smoking disease and no significant asbestos disease is understood. This may be properly accomplished through a requirement that total lung capacity (TLC) be abnormally high (over 120).

Considering the 79 non-malignant deaths secondary to asbestos related disease in the CARD mortality study 12/29/08, only 16% (13/79) met all medical criteria in the TDP for "Severe Disabling Pleural Disease."

81. Attached is a CD containing spreadsheets titled "CT Measurements by Dr. Whitehouse on various clients of MHSM and LSK," and "Chest x-ray measurements by Dr. Whitehouse on various clients of MHSM and LSK." Only one of the listed patients of the CARD Clinic (Robert Barnes) met all medical criteria for "severe pleural" under the Grace Plan.

82. Dr. Whitehouse will testify to opinions in medical records (already delivered) on patients who are Libby Claimants, and that each has a

probability of death with ARD as a significant contributing factor, for each of the following CARD patients:

1. Patients listed on CD "CHX measurements by Dr. Whitehouse on various clients of MHSM and LSK," report ¶ 81.
2. Patients listed on Exh. 6, rapid progression.
3. Patients and individuals listed on Exh. 9, mesotheliomas.
4. Patients on the CD "Plaques to Interstitial Disease" (Al Dickerman and Lloyd Brickey), Exh. list, item 6.
5. Patients listed on the CD "CARD Mortality Study Spreadsheets 5/09," spreadsheet "CARD Mortality Study 76 non-malignant deaths, and CHX reads by Dr. Whitehouse."
6. Patients referenced above who are not clients of MHSM or LSK, and for whom medical records have been delivered will also be discussed.

83. On Exh. 3, Whitehouse et al (2008), Table 1, medical records can be traced as follows:

- |                       |                      |                      |
|-----------------------|----------------------|----------------------|
| 1. Marvin Flatt       | 2. Carol Gerard      | 3. Jack Harrison     |
| 4. Loretta Orem       | 5. Arnold Pederson   | 6. Darlene Riley     |
| 7. James Roberts      | 8. Everett Sanderson | 9. Victoria Skidmore |
| 10. Elizabeth Trimble | 11. Ford Wilson      |                      |

84. The data and other information considered in forming the above opinions and observations include:


- a. Unless otherwise indicated, observations made in litigation are based upon the approximately 950 persons with ARD who are

clients of MHSM and LSK, and specific non-client patients who are listed on the documents in ¶ 82, for whom redacted medical records have been delivered. This is a very large number, and provides sufficient data to describe all phenomena discussed in this report.

- b. All information referenced above.
- c. Medical literature on asbestos disease.
- d. Consultations with Dr. Arthur Frank, and his expert report.
- e. Consultations with epidemiologist Dr. Craig Molgaard.
- f. A listing of cases with trial or deposition testimony is attached.

Compensation is at the rate of \$350 per hour.

DATED this <sup>th</sup>14 day of May, 2009.

  
Dr. Alan C. Whitehouse

### **List of Exhibits to Expert Report by Dr. Alan C. Whitehouse**

1. Whitehouse, A.C., Curriculum vitae.
2. "Asbestos-Related Pleural Disease Due to Tremolite Associated with Progressive Loss of Lung Function: Serial Observations in 123 Miners, Family Members, and Residents of Libby, Montana," Am J Ind Med 46:219-225 (2004).
3. "Environmental Exposure to Libby Asbestos and Mesotheliomas," Whitehouse (2008) Am J Ind Med. 51(11):877-880.
4. Client Sort by Exposure (Community/Family Member/Worker) (CARD patients only).
5. Dead in 123 patients in Whitehouse (2004), as of 3/12/09.
6. Chart "Case # Type of Progression" with x-rays on CD "Whitehouse Progression films." Also CD "Plaque to Interstitial Disease," and CD "photos of pleural plaques." (3/14/09)
7. Chart, "Summary of Mortality Study Disease Percentages."

Mortality data are on a CD titled "Mortality Study Spreadsheets," revised May 2009 containing spreadsheets on 76 non-malignant ARD deaths, 34 cancer deaths, and death certificate information for 110 deaths.

"CARD Mortality Study, 76 Non-Malignant Deaths, CHX Readings by Dr. Whitehouse." May 2009.

"CARD Mortality Study, Meso, LC, Other Cancers, CHX Readings by Dr. Whitehouse." May 2009.

"CARD Mortality Study, 76 non-malignant deaths, CT Scans per Dr. Whitehouse." May 2009.

"CARD Mortality Study, 76 Non-Malignant Deaths, CHX Readings by Dr. Frank." May 2009.



"CARD Mortality Study, non-malignant ARD deaths - primary/contributing causes 5/9/09."

"Death Certificate Causes of Death 110." May 2009.

Mortality study medical records 116, Exh. 7 is a separate CD revised 5/09. Patient information on non clients is redacted. See "116 Mortality List" with "Patient Number on CD" attached to this list.

- 7a. Chart, "Summary of Mortality Study Disease Percentages Primary Cause Analysis (as of 7/9/08)."
8. Printout, "Libby Claimants on Oxygen (CARD patients only)," 5/28/08 and "Libby Claimants with FVC, TLC or DLCO < 60 (CARD patients only)," 5/28/08.
9. Chart "Mesothelioma Cases Due to Exposure to Libby Asbestos." Documents supporting the chart are on the CD titled "Meso Cases Libby 7/30/07."
10. "Summary of Deceased Clients Chart MHSM" and "Summary of Deceased Clients Chart MHSM" with supporting data summaries.
11. Charts 035a "Workers with Disease - 1969," 035b "Workers with Disease - 1975," and 035c "Workers with Disease - 1976."
12. Cookson (1986), Fig. 1. Chart W-2 "Years since first exposed."
13. Chart, Studies on Radiographic Progression of Asbestos Disease.
14. Chart, Workers Dead from Asbestos Disease (2000 study).
15. Audit of HNA Denials and Downgrades of Severity of Disease (December 2005), and chart of data with non-Libby Claimants deleted.
16. Public Citizen, "Leading Medical Experts Fault Arbitrary, Outdated Medical Criteria in Asbestos Bill," (May 2005).
17. Letter dated February 9, 2005, titled "Preliminary Report of 79 Chest X-rays Reviewed Relative to the Asbestos Injury Resolution Act of 2005,

with attached Log of Patients Criteria Study, FVC and on Oxygen (non-Libby Claimants' names are blacked out.)

18. Letter by the President of the American Thoracic Society.
19. Chart, "Weill comparison to ATSDR and CARD." Documents supporting the chart are on the CD titled "Weill Comparison 7/23/07."
20. W.R. Grace & Co., "Source Emissions - Results of Surveys 1975."
21. Chart, "Libby Cohort Deaths Per Source."
22. W.R. Grace & Co., memo, McCaig to Walsh 9/17/85.
23. Chart, "Center for Asbestos Related Disease, Libby Pulmonary Function Test (PFT) Comparison with Independent Medical Exam PFTs." Documents supporting the chart are on the CD titled "CARD PFT Comparison with IME PFTS 7/23/07."
24. Listing of cases with deposition or trial testimony.